K020789

Section 2:
510(k) Summary
Per 21 CFR Part 807.92.

APR 0 4 2002

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Safety and Regulatory Engineering
Telephone: 414-647-4385, Fax: 414-647-4090

Date Prepared: March 8, 2002

2. Device Name: GE Vivid 3 Expert/Pro Diagnostic Ultrasound System.
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: GE Vivid 3 Expert/Pro is substantially equivalent to the GE Vivid 3 system, 510(k) Number K000695, a device currently in commercial distribution.

4. Device Description: The GE Vivid 3 Pro and Expert are minor variations of the Vivid 3 suited for slightly different market segments. The Expert version provides more features as standard equipment while the Pro version, having fewer base options, allows features to be added if desired. Both systems consists of a mobile console with digital beam former and assorted electronic array transducers. Their user interface consists of a keyboard control panel and color video display monitor. They are network accessible and have integrated on-board image storage and hard-copy devices.

5. Indications for Use: The GE Vivid 3 Expert/Pro systems are general purpose ultrasound systems that are specialized for cardiac imaging. Specific clinical uses include cardiac (adult & pediatric); peripheral vascular; transesophageal; abdominal including GYN and urology; fetal; pediatric; small organ including breast, testes, thyroid; adult and neonatal cephalic; intraoperative (abdominal, thoracic, and vascular); musculo-skeletal (conventional and superficial); transvaginal and transrectal.

6. Comparison with Predicate Device: The GE Vivid 3 Expert/Pro systems are of comparable type and substantially equivalent to the GE Vivid 3. They have the same technological characteristics, compare in key safety and effectiveness features, use same design, construction, and materials, and have similar intended uses, clinical applications, transducers and operating modes as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 9001 & EN 46001 quality system standards for medical device manufacturers. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing production surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vivid 3 Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Allen Schuh
Manager GE Ultrasound Product Safety
and Regulatory Compliance
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

APR 0 4 2002

Re: K020789
Trade Name: GE Vivid 3 Expert/Pro Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: 90 IYN
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: March 8, 2002
Received: March 11, 2002

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid 3 Expert/Pro Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

E721 Transducer
i12L Transducer

i8L Transducer
i13L Transducer
i739 or t739 Transducer
7L Transducer
12L Transducer
5S Transducer
10S Transducer
6T Transducer
8T Transducer
P6D Transducer
P509 Transducer
358C Transducer
10L Transducer
3S Transducer
7S Transducer
5T Transducer
P2D Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)[2]	P	P	P		P		P	P	E		
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular	P	P	P	P	P		P	P	E		
Musculo-skeletal Conventional	P	P	P		P		P	P	E		
Musculo-skeletal Superficial	P	P	P		P		P	P	E		
Other[4]	P	P	P	P	P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal	N	N	N		N		N	N	N		
Transvaginal	N	N	N		N		N	N	N		
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	E		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with E721 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N		N	N	N		
Abdominal[1]	N	N	N		N		N	N	N		
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N		N		N	N	N		
Exam Type, Means of Access											
Transesophageal											
Transrectal	N	N	N		N		N	N	N		
Transvaginal	N	N	N		N		N	N	N		
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with i12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N		N	N	N		
Pediatric	N	N	N		N		N	N	N		
Small Organ (specify)[2]	N	N	N		N		N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N		N		N	N	N		
Peripheral Vascular	N	N	N		N		N	N	N		
Musculo-skeletal Conventional	N	N	N		N		N	N	N		
Musculo-skeletal Superficial	N	N	N		N		N	N	N		
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	N	N	N		N		N	N	N		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with i8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N		N	N	N		
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N		N		N	N	N		
Peripheral Vascular	N	N	N		N		N	N	N		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	N	N	N		N		N	N	N		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020781

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with i13L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N		N	N	N		
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N		N		N	N	N		
Peripheral Vascular	N	N	N		N		N	N	N		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	N	N	N		N		N	N	N		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020784

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with i739 or t739 Transducers

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	E	E	E		E		E	E	E		
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E		E		E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	E	E	E		E		E	E	E		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyt

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 7L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	E	E	E		E		E	E	E		
Small Organ (specify)[2]	E	E	E		E		E	E	E		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	E	E	E		E		E	E	E		
Musculo-skeletal Conventional	E	E	E		E		E	E	E		
Musculo-skeletal Superficial	E	E	E		E		E	E	E		
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	E	E	E		E		E	E	E		
Small Organ (specify)[2]	E	E	E		E		E	E	E		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	E	E	E		E		E	E	E		
Musculo-skeletal Conventional	E	E	E		E		E	E	E		
Musculo-skeletal Superficial	E	E	E		E		E	E	E		
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	E	E	E		E		E	E	E		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 5S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	E	E	E	E	E	E	E	E	E		
Abdominal[1]	E	E	E	E	E	E	E	E	E		
Pediatric	E	E	E	E	E	E	E	E	E		
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E	E	E		
Cardiac[3]	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 10S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	E	E	E	E	E	E	E	E	E		
Pediatric	E	E	E	E	E	E	E	E	E		
Small Organ (specify)[2]											
Neonatal Cephalic	E	E	E	E	E	E	E	E	E		
Adult Cephalic	E	E	E	E	E	E	E	E	E		
Cardiac[3]	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 6T Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 8T Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]			E	E							
Peripheral Vascular			E	E							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with P509 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 358C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	E		
Abdominal[1]	P	P	P		P		P	P	E		
Pediatric	P	P	P		P		P	P	E		
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 10L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	E		
Abdominal[1]											
Pediatric	P	P	P		P		P	P	E		
Small Organ (specify)[2]	P	P	P		P		P	P	E		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P		P	P	E		
Musculo-skeletal Conventional	P	P	P		P		P	P	E		
Musculo-skeletal Superficial	P	P	P		P		P	P	E		
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	E		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020739

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 7S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with 5T Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K020789

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 3 Expert/Pro with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020789